EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Plaintiffs*, v. MODERNA, INC. and MODERNATX, INC., *Defendants*.	C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., *Counterclaim-Plaintiffs*, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH, *Counterclaim- Defendants.*	

AMICUS CURIEA BRIEF OF ALLIANCE OF U.S. STARTUPS AND INVENTORS FOR JOBS ("USIJ) IN SUPPORT OF NEITHER PARTY

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Amicus curiae Alliance of U.S. Startups and Inventors for Jobs ("USIJ") submits this brief to bring to the Court's attention an important issue related to the application of 35 U.S.C. §1498, an issue which if dealt with incorrectly, could precipitate a major upheaval in the entrepreneurial ecosystem of our country.

I. Interest of USIJ

USIJ is a coalition of startup companies, inventors, investors, and entrepreneurs whose businesses depend upon stable and reliable patent protection as an essential foundation for making long-term investments of capital and time commitments to high-risk ventures developing new technologies. USIJ was formed in 2012 to address concerns that legislation, policies and practices adopted by the U.S. Congress, the Federal Judiciary and certain Federal agencies were and are placing individual inventors, entrepreneurs and research-intensive startups ("USIJ Cohort") at an unsustainable disadvantage relative to their larger incumbent rivals, both domestic and foreign, and others that would make wrongful use of their inventions and patents. USIJ's fundamental mission is to bring attention to the critical role that patents play in our nation's economic health and to the particular importance of startups and small companies in that regard. A disproportionately large number of strategically critical breakthrough inventions are attributable to such individual inventors and small companies. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* made a monetary contribution to its preparation or submission

II. Introduction and Summary.

USIJ submits this *amicus* brief to emphasize an important – indeed critical – distinction that must be maintained between (a) the proper use of Section 1498, which allows the Federal

Government to take property for its own consumption and/or use, and (b) the improper expansion of Section 1498 in ways that could allow politicians and bureaucrats to circumvent the strictures of the Bayh-Dole Act (35 U.S.C. §§ 200 – 209) that currently prevent Government control of the retail pricing of drugs and other patented products. For years, consumer groups have demanded that the Government mandate lower prices on patented drugs, irrespective of the destructive impact price controls would have on future investments in the continued development of new medicines and medical devices. These demands are echoed by a few politicians who argue that any patented invention that incorporates scientific research funded in some part by the Federal Government should be subject to Government price controls.[1]

USIJ takes no position with respect to the merits or outcome of the patent dispute between Arbutus Biopharma and Moderna insofar as it relates to contract issues or products delivered to the U.S. Government for the Government's own consumption. We are concerned, however, because Moderna appears to be inviting the Court to take a more expansive view of Section 1498 that would include undefined and vague "government interests" that the legislation was never intended to cover. This has potential implications for the proper interpretation of both Section 1498 as well as for the March-in Provision of the Bayh-Dole Act (Section 203), as it may relate to

[1] *E.g.*, https://www.sanders.senate.gov/press-releases/news-sanders-statement-on-white-house-proposal-to-consider-price-as-a-factor-in-breaking-patent-monopolies-on-some-taxpayer-funded-prescription-drugs/#:~:text=On%20December%207%2C%202023%2C%20Senator%20Bernie%20Sanders,to%20manufacture%20generic%20versions%20of%20this%20treatment; *accord*: Adam Cancryn, "Bernie Sanders is personally stopping Biden's top medical research nominee — and he's not budging," Politico, 7/11/2023. The Cancryn article points out that Senator Sanders, as chair of relevant Senate committee, was holding up the appointment of a Director for NIH to obtain an agreement to force drug companies to sell at lower prices. https://www.politico.com/news/2023/07/11/sanders-biden-nih-nominee-00105738.

hundreds or thousands of patents and products. USIJ respectfully submits that any ambiguity in a ruling by this Court as to the scope of Section 1498 could wreak havoc in the flow of capital and human resources necessary to develop new drugs and other science-based products.

USIJ is concerned specifically with the likelihood that any interpretation expanding the concept of what is "for the Government" is likely to be ambiguous in scope and could be seized upon by the same consumer groups and politicians, discussed *supra*, who have pushed unsuccessfully for the use of "march in rights" to control the prices paid by the public for patented drugs and other products. These entities are now turning to Section 1498 to achieve the same objective.[2] Experience has demonstrated time and again that even well-intentioned governmental efforts to control prices turn out to be a bad idea.[3]

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[2] *E.g.*, Brennan, et.al., "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," 18 Yale L. Journ. 275, 284 (2016); Kapczynski & Kesselheim, "Government Patent Use: A Legal Approach to Reducing Drug Spending," 35 Health Affairs 791 (2016) (claiming that "new medicines . . . are expensive not because they are expensive to manufacture but because they are protected by patents"); Engelberg, *et al*, "A New Way to Contain Unaffordable Medication Costs—Exercising the Government's Existing Rights," 386 New England J. of Medicine 1104 - 1106 (2022) (urging use of Section 1498 for nullifying patent protection).

[3] *E.g.*, Letter dated March 23, 2023 from U.S. Chamber of Commerce to Senators Bernie Sanders and Bill Cassidy, Chair and Ranking Member of the Committee on Health, Education, Labor, and Pensions, https://www.uschamber.com/assets/documents/230322_Hearing_COVIDVaxPrice_HELP.pdf, which notes that:

> "[D]rug pricing penalties will actually harm patients by causing them to forfeit early and extensive access to the best life-saving medications. … in other OECD countries which have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicines." p.2.

That letter covers a number of related topics, noting *inter alia* that in some European countries, patients must wait over a year to get access to life-saving drugs.

See also, Schuettinger and Butler, FORTY CENTURIES OF WAGE AND PRICE CONTROLS: HOW NOT TO FIGHT INFLATION, Heritage Foundation (1979).

There are too many facets of this extremely complex problem to cover fully in an *amicus* brief to this Court. We refer the Court, however, to a well-reasoned and informative academic paper by Prof. Adam Mossoff of George Mason University – Antonin Scalia Law School, entitled "The False Promise of Breaking Patents to Lower Drug Prices," St. John's Law Review, 98: 287-2338 (2024), which explains the legal history and legislative intent in considerable detail. That paper discusses the many reasons why neither the march-in provision in the Bayh-Dole Act nor Section 1498 can properly be construed for such an outcome.[4]

III. The Bayh-Dole Act (35 U.S.C. §§200-209) Defines a Specific Role for the Federal Government Regarding New Drugs.

More than half of all new therapies and drug products are developed and brought to market by startup companies supported by venture capital investors.[5] Some of these drugs are developed in part in reliance on exclusive licenses to commercialize scientific research funded through federal grants to research labs and universities throughout the country. Such licenses are allowed by the Bayh-Dole Act (35 U.S.C. §§ 200-209), which was enacted in 1980 to promote the commercialization of federally funded scientific research. Prior to that time, more than 30 years of extensive funding of scientific research had not resulted in any significant commercialization of technology for the benefit of the American public.[6] Despite efforts to encourage

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HTTPS://CDN.MISES.ORG/FORTY%20CENTURIES%20OF%20WAGE%20AND%20PRICE%20CONTROLS%20HOW%20NOT%20TO%20FIGHT%20INFLATION_2.PDF.

[4] *See,* https://scholarship.law.stjohns.edu/lawreview/vol98/iss2/5; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4348499#.

[5] See, e.g, Shivakumar, Sirkar, and Depp "Understanding the U.S. Biopharmaceutical Innovation Ecosystem," https://www.csis.org/analysis/understanding-us-biopharmaceutical-innovation-ecosystem, p.8.

[6] Commencing shortly after WWII, a number of federal agencies continued to invest in various types of scientific research that had proved to be instrumental in our nation's victory over Germany and Japan. For nearly 35 years, that research led to thousands of patents and research

commercialization of such research by both the government agencies approving the research grants and the grant recipients themselves, there was little or no interest on the part of any private company with sufficient financial wherewithal to try and commercialize new technology that was owned and controlled by the Federal Government. Not a single product from this early effort was ever commercialized during the 35 years prior to 1980. In the parlance of investors – "the potential reward was not worth the risk."

That situation changed with passage of the Bayh-Dole Act, which provided that patents covering technology derived from federally funded research could be licensed exclusively to the grant recipient – often a university in the case of new drugs and therapies.[7] This, in turn, created incentives for universities and professors to find ways to commercialize their discoveries, and led to a virtual explosion of new investments resulting in hundreds of new drugs and therapies as well as other types of products.[8] Although exact estimates are difficult to calculate, the Association of University Technology Managers ("AUTM") has reported that, from 1996 until 2020, over 200 new drugs and vaccines were brought to market through university-industry partnerships made possible by the Bayh-Dole Act.[9]

The benefits of the Bayh-Dole Act were not limited to medicines and medical devices. Other technologies funded in part by federal grants also were used to create products pursuant to

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papers whose ownership was held by the Federal Government itself, none of which was ever commercialized for the benefit of the American public.

[7] An exclusive license is essentially an irrevocable assignment for most purposes, although the Act does provide in Section 209(d)(3) that under certain limited circumstances, the Government can revoke either the license itself or the exclusivity provision, where the licensee fails to commercialize the invention as intended.

[8] *See, e.g,* Shivakumar, Sirkar, and Depp "Understanding the U.S. Biopharmaceutical Innovation Ecosystem," https://www.csis.org/analysis/understanding-us-biopharmaceutical-innovation-ecosystem, p.8.

[9] *Id.*

licenses granted by universities and research labs, including, most notably, Google's fundamental page-ranking patent developed at Stanford University and licensed to the entrepreneurs who created Google.[10] These university licensing programs implementing the Bayh-Dole Act gave rise to a "virtuous cycle" in which the developer of a new drug or product pay royalties to the university that granted the license, which in turn enjoys revenues for funding additional research.[11]

IV. Some Politicians Would Like to Impose Government Price Controls on Patented Drugs Originally Licensed Under the Bayh-Dole Act

Despite the astounding success of the Bayh-Dole Act, a number of politicians and companies that would benefit from lower prices on medicines have encouraged the use the so-called "march-in" provision found in 35 U.S.C. § 203 to control the price at which a commercialized product is sold to the public – drugs and medical devices for the most part. For any agency to do so, however, would require twisting the meaning of the statutory language and would have disastrous consequences for the virtuous cycle that the Bayh-Dole Act has spawned. From the time of passage in 1980 until 2023, numerous such efforts were rejected, because the Bayh-Dole Act does not make any reference to the pricing of end products and makes clear that the march-in rights are limited to situations in which the licensee is unable or unwilling to commercialize the intended product.[12]

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[10] https://nsjonline.com/article/2020/07/ku-a-little-known-law-gave-birth-to-google-and-countless-other-inventions

[11] In its 2005 Annual Technology Report, Stanford University reported receiving $336 million for its equity shares of Google, which began as a startup. The report also noted:

> "What have we accomplished in 35 years? We've evaluated over 6,000 inventions, obtained 1,500 U.S. patents, entered into 2,500 licenses and option agreements, and brought in over one billion dollars in licensing revenue. https://web.stanford.edu/group/OTL/documents/otlar05.pdf.

[12] *See, e.g.*, letter dated January 17, 2024 from Joseph Allen on behalf of the Bayh-Dole Coalition to Hon. Laurie E. Locasio, Director of NIST. The letter also sets forth a number of reasons the Framework proposal would not be allowed under the Bayh-Dole Act, and in any event

In 2023, however, an "interagency working group" within the Biden Administration, headed by the National Institute of Standards & Technology ("NIST"), issued a proposal to reinterpret Section 203 in a way that would allow the Government to control the price of any product to whose development the Federal Government had contributed any portion of the total funding, no matter how small. The group proposed the creation of a "Framework" that could use the march-in provision in a number of different situations, with "reasonable pricing" being the dominant factor identified. That proposal was allowed to die after the vast majority of companies that rely on patents to raise capital and justify risky undertakings, voiced vehement opposition. The National Venture Capital Association, for example, was explicit that the effect of the Framework would "make public funding toxic for VCs."[13] The Bayh-Dole Coalition response made a similar point:

> "The [Framework proposal would] return us to the pre-Bayh-Dole days when federal funding was toxic. Under the [Framework proposal], anyone founding a start-up company or licensing a federally-funded invention has a target on their back as competitors, the unscrupulous, and even foreign adversaries can file march-in petitions objecting to the price of a successfully developed product based on a government-supported invention."[14]

Other objecting entities included the medical device and biopharma industries and countless other entities that rely on enforceable patents to justify investments in new technologies.

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why the proposal would not have affected the prices of the vast majority of patented drugs sold to the public. https://bayhdolecoalition.org/wp-content/uploads/2024/01/Bayh-Dole-Coalition-Comments-on-NIST-Draft-March-in-Framework-2.pdf#new_tab.

In 1989, NIH experimented with the idea of inserting a "reasonable pricing" requirement into some of the exclusive licenses that it granted to universities, but the effect was to drive away potential entrepreneurs and investors. In 1995, NIH abandoned the idea as a failure. *Id*. at p. 6.

[13] Letter to Hon. Joseph R. Biden, President, dated January 23, 2024, from Bobby Franklin, President and CEO of NVCA, addressing the NIST proposal. (https://nvca.org/wp-content/uploads/2024/01/NVCA_WH-Letter-on-March-In.pdf).

[14] https://bayhdolecoalition.org/wp-content/uploads/2024/01/Bayh-Dole-Coalition-Comments-on-NIST-Draft-March-in-Framework-2.pdf#new_tab.

USIJ's opposition can be found at https://usij.org/wp-content/uploads/2024/07/USIJResponsetoNISTBayhDoleGuidanceRFI.pdf.

The Framework proposal was quietly allowed to die with the 2024 election and the change of Administrations, but the fervent effort to establish price controls lingers on and now includes erroneous assertions that Section 1498 also gives agencies the power to control prices.

V. The Construction of Section 1498 Suggested by Moderna Is Not Supportable by Either the Language or Intent of the Provision.

Just as the Bayh-Dole Act does not allow the Government to control prices of medicines and other patented products, neither does Section 1498. The statute sets forth clearly the basis for initiating a lawsuit against the Federal Government to address patent infringement:

> "Whenever an invention described in and covered by a patent of the United States is **used or manufactured by or for the United States** without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture …." *Id*., subsection (a).

As noted by Professor Mossoff (See fn.4 and accompanying text), this statute essentially confers on the Government the power of eminent domain to condemn private property for Government use. The brief submitted by Moderna in support of its motion for summary judgment, however, is unclear as to what constitutes use or manufacture "by or for the United States," as required in the statute. For example, Moderna states:

> "[E]ven if the court were to decide that – despite the plain language of the contract and precedent to the contrary – it was appropriate to reassess whether the government **benefited**, there is still no genuine dispute that the provision of COVID-19 vaccine doses under the C-100 Contract was 'for' the Government's **benefit**." (emphasis supplied) (Mot., p.15).

In support of this proposition, Moderna's brief cites language from a district court decision in *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963 (C.D. Cal. 2019) ("a use

is 'for the Government' if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for the Government's benefit'").

The actual holding in the *Saint-Gobain* case does not support this statement – *i.e.*, the case involves a patented composition of matter sold to and consumed by the Federal Government. The language cited by Moderna, however, is a bridge too far. The language is ambiguous in that it could be construed to mean that any Government agency can authorize a company, other than the owner or licensee of a patent, to infringe a patent and deliver infringing products to some segment of the public instead of the Government "in furtherance and fulfillment of a stated Government policy." We respectfully submit that adoption of such an interpretation of Section 1498 by any Federal agency will undermine severely the reliability of U.S. patents and grossly distort the intent of the legislation creating this Section. The jurisprudence under Section 1498 is reasonably clear that product "used or manufactured by or for the United States" is triggered only when products are delivered to and consumed by the Government. Any broader interpretation of the language will have a serious and adverse impact on the willingness of entrepreneurs and investors to pursue high risk projects, such as new drug development, that have a long and expensive development cycle and are therefore dependent upon the existence of reliable patents to recover years of investing.[15]

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[15] Patent risk in this circumstance is merely one of several risk factors that must be accounted for in any decision to make an initial investment of human and financial capital, starting with the point that only 13% of development projects actually result in an approved drug. Execution risks, the inability to obtain follow-on investments, the failure of FDA to approve either the safety or efficacy of a drug, all make these very risky investments. https://www.csis.org/analysis/understanding-us-biopharmaceutical-innovation-ecosystem, p. 8.

A report entitled "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," published in the Journal of Health Economics 47 (2016) describes a study of 106 new drugs developed by 10 different companies. The study estimates the average cost per drug at $1.4B without considering the time-value of the out-of-pocket investments. If a reasonable cost of funds is added, the total average cost is $2.8B per drug. https://pubmed.ncbi.nlm.nih.gov/26928437.

VI. Conclusion

USIJ urges the Court to avoid making any ruling in this case that would expand the scope of Section 1498 by giving a broader meaning than was intended by the statute. The term "for the Government," as we read it, means products delivered to the Government for consumption and/or use by the Government. The statute requires more than some vaguely structured "authorization" to one or more competitors of a patented product to infringe the relevant patents and send the bill to the Federal Government.

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